

WE CLAIM:

1. An oral pharmaceutical composition of fenofibrate comprising an inert hydro-insoluble carrier having one or more one layers comprising fenofibrate in a micronized form, a hydrophilic polymer, and a surfactant.
2. The composition of claim 1, further comprising two or more outer phases or layers.
3. The composition of claim 2, wherein the two or more outer phases or layers comprise one or more of fenofibrate in a micronized form, a hydrophilic polymer, and a surfactant.
4. The composition of claim 1, wherein the micronized fenofibrate has a size less than or equal to about 20 microns.
5. The composition of claim 1, wherein the micronized fenofibrate has a size less than or equal to about 10 microns.
6. The composition of claim 1, wherein the micronized fenofibrate comprises an amount of from about 20% w/w to about 45% w/w of the composition.
7. The composition of claim 1, wherein the hydro-insoluble carrier comprises one or more of microcrystalline cellulose, dicalcium phosphate and pregelatinized starch.
8. The composition of claim 1, wherein the hydro-insoluble carrier comprises an amount of from about 20% w/w to about 60% w/w of the composition.
9. The composition of claim 1, wherein the hydrophilic polymer comprises one or more of polyvinyl pyrrolidone, hydroxy propyl cellulose, hydroxypropyl methylcellulose, polyvinyl alcohol, and gelatin.
10. The composition of claim 1, wherein the hydrophilic polymer comprises an amount of from about 10% w/w to about 45% w/w of the composition.
11. The composition of claim 1, wherein the surfactant comprises one or more of sodium lauryl sulphate, monoleate, monolaurate, monopalmitate, monostearate or other esters of polyoxyethylene sorbitan, polyethylene glycol laurate, lecithins, propylene glycol alginate, bile acids, phospholipids, and propylene glycol laurate.
12. The composition of claim 1, wherein the surfactant comprises an amount of from about 0.5% w/w to about 3.0% w/w of the composition.

- 1 13. The composition of claim 1, wherein the composition further comprises one or more
2 pharmaceutically acceptable excipients comprising disintegrants, binders, fillers,
3 glidants, lubricants, colorants, wetting agents, buffers, and coatings.
- 1 14. The composition of claim 13, wherein the disintegrant comprises one or more of
2 croscarmellose sodium, cross-linked polyvinyl pyrrolidone and sodium starch
3 glycolate.
- 1 15. The composition of claim 13, wherein the filler comprises one or more of
2 microcrystalline cellulose, lactose, starch, and cross-linked polyvinyl pyrrolidone.
- 1 16. The composition of claim 13, wherein the binder comprises one or more of
2 hydroxypropyl methylcellulose, hydroxypropyl cellulose, gelatin, and polyvinyl
3 pyrrolidone.
- 1 17. The composition of claim 13, wherein the glidant comprises one or more of starch,
2 talc, stearates, and colloidal silicon dioxide.
- 1 18. The composition of claim 13, wherein the lubricant comprises one or more of stearic
2 acid, talc, sodium stearyl fumarate, mineral oil, and magnesium stearate.
- 1 19. The composition of claim 1, wherein the composition comprises one or more of
2 granules, tablets, capsules, dry syrup, suspension, and sachets.
- 1 20. The composition of claim 1, wherein the composition further comprises one or more
2 of simvastatin, lovastatin, atorvastatin, pravastatin, fluvastatin, cerivastatin,
3 rosuvastatin, metformin, niacin, folic acid, and losartan.
- 1 21. The composition of claim 20, wherein the fenofibrate and the one or more active
2 ingredients are combined in a single pharmaceutical composition.
- 1 22. The composition of claim 1, wherein the composition has a dissolution of at least
2 about 10% in about 5 minutes, about 20% in about 10 minutes, about 50% in about 20
3 minutes, and about 75% in about 30 minutes, as measured using the rotating blade
4 method at 75 rpm according to the European Pharmacopoeia in a dissolution medium
5 constituted by water with 2% by weight of Polysorbate 80 or with 0.025M sodium
6 lauryl sulphate.
- 1 23. An oral pharmaceutical composition comprising from about 20% w/w to about 45%
2 w/w of micronized fenofibrate, from about 10% w/w to about 45% w/w of one or
3 more hydrophilic polymers, from about 0.5% w/w to about 3.0% w/w of one or more

4 surfactants, and from about 20% w/w to about 60% w/w of one or more inert hydro-
5 insoluble carriers.

1 24. The composition of claim 23, wherein the micronized fenofibrate has a size less than
2 or equal to about 20 microns.

1 25. The composition of claim 23 wherein the hydro-insoluble carrier comprises one or
2 more of microcrystalline cellulose, dicalcium phosphate and pregelatinized starch.

1 26. The composition of claim 23, wherein the hydrophilic polymer comprises one or more
2 of polyvinyl pyrrolidone, hydroxy propyl cellulose, hydroxypropyl methylcellulose,
3 polyvinyl alcohol and gelatin.

1 27. The composition of claim 23, wherein the surfactant comprises one or more of sodium
2 lauryl sulphate, monoleate, monolaurate, monopalmitate, monostearate or other esters
3 of polyoxyethylene sorbitan, polyethylene glycol laurate, lecithins, propylene glycol
4 alginate, bile acids, phospholipids and propylene glycol laurate.

1 28. The composition of claim 23, wherein the composition further comprises one or more
2 of simvastatin, lovastatin, atorvastatin, pravastatin, fluvastatin, cerivastatin,
3 rosuvastatin, metformin, niacin, folic acid and losartan.

1 29. The composition of claim 23, wherein the composition has a dissolution of at least
2 about 10% in about 5 minutes, about 20% in about 10 minutes, about 50% in about 20
3 minutes, and about 75% in about 30 minutes, as measured using the rotating blade
4 method at 75 rpm according to the European Pharmacopoeia in a dissolution medium
5 constituted by water with 2% by weight of Polysorbate 80 or with 0.025M sodium
6 lauryl sulphate.

1 30. A process for preparing a pharmaceutical composition of fenofibrate and having an
2 improved dissolution profile, the process comprising:

3 a. mixing micronized fenofibrate, one or more hydrophilic polymers and one or
4 more surfactants to obtain a solution or dispersion, and

5 b. layering the solution or dispersion onto a hydro-insoluble carrier to obtain
6 granulates.

1 31. The process of claim 30, further comprising mixing the granulates with one or more
2 pharmaceutically acceptable excipients selected from the group comprising one or

3 more of fillers, binders, disintegrants, lubricants, glidants, colorants, lubricants,
4 wetting agents, buffers, and flavoring agents to obtain a mixture.

1 32. The process of claim 30, further comprising processing the granulates to obtain the
2 pharmaceutical composition, wherein the pharmaceutical composition has a
3 dissolution profile of at least about 10% in about 5 minutes, about 20% in about 10
4 minutes, about 50% in about 20 minutes and about 75% in about 30 minutes, as
5 measured using the rotating blade method at 75 rpm according to the European
6 Pharmacopoeia in a dissolution medium constituted by water with 2% by weight of
7 Polysorbate 80 or with 0.025M sodium lauryl sulphate.

1 33. The process of claim 31, further comprising processing the mixture to obtain the
2 pharmaceutical composition, wherein the pharmaceutical composition has a
3 dissolution profile of at least about 10% in about 5 minutes, about 20% in about 10
4 minutes, about 50% in about 20 minutes and about 75% in about 30 minutes, as
5 measured using the rotating blade method at 75 rpm according to the European
6 Pharmacopoeia in a dissolution medium constituted by water with 2% by weight of
7 Polysorbate 80 or with 0.025M sodium lauryl sulphate.

1 34. The process of claim 30, wherein the micronized fenofibrate has a size less than or
2 equal to about 20 microns.

1 35. The process of claim 30, wherein the micronized fenofibrate comprises an amount of
2 from about 20% w/w to about 45% w/w of the composition.

1 36. The process of claim 30, wherein the hydro-insoluble carrier is selected from the
2 group comprising one or more of microcrystalline cellulose, dicalcium phosphate and
3 pregelatinized starch.

1 37. The process of claim 30, wherein the hydro-insoluble carrier comprises an amount of
2 from about 20% w/w to about 60% w/w of the composition.

1 38. The process of claim 30, wherein the hydrophilic polymer is selected from the group
2 comprising one or more of polyvinyl pyrrolidone, hydroxy propyl cellulose,
3 hydroxypropyl methylcellulose, polyvinyl alcohol and gelatin.

1 39. The process of claim 30, wherein the hydrophilic polymer comprises an amount of
2 from about 10% w/w to about 45% w/w of the composition.

- 1 40. The process of claim 30, wherein the surfactant is selected from the group comprising
2 one or more of sodium lauryl sulphate, monoleate, monolaurate, monopalmitate,
3 monostearate or other esters of polyoxyethylene sorbitan, polyethylene glycol laurate,
4 lecithins, propylene glycol alginate, bile acids, phospholipids, and propylene glycol
5 laurate.
- 1 41. The process of claim 30, wherein the surfactant comprises an amount of from about
2 0.5% w/w to about 3.0% w/w of the composition.
- 1 42. The process of claim 30, wherein the composition comprises one or more of granules,
2 tablets, capsules, dry syrup, suspensions or sachets.
- 1 43. The process of claim 30, further comprises adding one or more of simvastatin,
2 lovastatin, atorvastatin, pravastatin, fluvastatin, cerivastatin, rosuvastatin, metformin,
3 niacin, folic acid and losartan.
- 1 44. A method of treating one or more of hyperlipidemia, hypercholesterolemia and
2 hypertriglyceridemia, the method comprising administering an oral pharmaceutical
3 composition of fenofibrate comprising an inert hydro-insoluble carrier with at least
4 one layer containing fenofibrate in a micronized form, one or more hydrophilic
5 polymers and one or more surfactants.
- 1 45. The method of claim 44, wherein the composition further comprises one or more
2 outer phases or layers.
- 1 46. The method of claim 45, wherein the two or more outer phases or layers comprise one
2 or more of fenofibrate in a micronized form, one or more hydrophilic polymers, and
3 one or more surfactants.
- 1 47. The method of claim 44, wherein the micronized fenofibrate has a size less than or
2 equal to about 20 microns.
- 1 48. The method of claim 44, wherein the micronized fenofibrate comprises an amount of
2 from about 20% w/w to about 45% w/w of the composition.
- 1 49. The method of claim 44, wherein the hydro-insoluble carrier comprises one or more
2 of microcrystalline cellulose, dicalcium phosphate and pregelatinized starch.
- 1 50. The method of claim 44, wherein the hydro-insoluble carrier comprises an amount of
2 from about 20% w/w to about 60% w/w of the composition.

- 1 51. The method of claim 44, wherein the hydrophilic polymer comprises one or more of
2 polyvinyl pyrrolidone, hydroxy propyl cellulose, hydroxypropyl methylcellulose,
3 polyvinyl alcohol, and gelatin.
- 1 52. The method of claim 44, wherein the hydrophilic polymer comprises an amount of
2 from about 10% w/w to about 45% w/w of the composition.
- 1 53. The method of claim 44, wherein the surfactant comprises one or more of sodium
2 lauryl sulphate, monooleate, monolaurate, monopalmitate, monostearate or other esters
3 of polyoxyethylene sorbitan, polyethylene glycol laurate, lecithins, propylene glycol
4 alginate, bile acids, phospholipids, and propylene glycol laurate.
- 1 54. The method of claim 44, wherein the surfactant comprises an amount of from about
2 0.5% w/w to about 3.0% w/w of the composition.
- 1 55. The method of claim 44, wherein the composition has a dissolution profile of at least
2 about 10% in about 5 minutes, about 20% in about 10 minutes, about 50% in about 20
3 minutes and about 75% in about 30 minutes, as measured using the rotating blade
4 method at 75 rpm according to the European Pharmacopoeia in a dissolution medium
5 constituted by water with 2% by weight of Polysorbate 80 or with 0.025M sodium
6 lauryl sulphate.